IN THE SUPREME COURT OF MISSOURI
EN BANC

No. 85275

STATE BOARD OF REGISTRATION FOR THE HEALING ARTS, Appellant

vs.

EDWARD W. MCDONAGH, Respondent

On Transfer from the Missouri Court of Appeals–Western District
WD# 60501

Appeal from the Circuit Court of Cole County, Missouri
Nineteenth Judicial Circuit
Honorable Byron Kinder, Circuit Judge

CORRECTED SUBSTITUTED REPLY BRIEF OF APPELLANT STATE BOARD OF REGISTRATION FOR THE HEALING ARTS

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ARGUMENT

POINT I.

THE ADMINISTRATIVE HEARING COMMISSION ERRED AND ABUSED ITS DISCRETION BY ADMITTING INTO EVIDENCE AND RELYING ON AS SUBSTANTIAL EVIDENCE RESPONDENT'S EXPERT MEDICAL TESTIMONY IN SUPPORT OF HIS USE OF EDTA CHELATION THERAPY TO TREAT ATHEROSCLEROSIS AND OTHER VASCULAR DISEASES, BECAUSE: (A) RESPONDENT'S EXPERT TESTIMONY DID NOT REST ON SCIENCE MEETING THE GENERAL ACCEPTANCE TEST UNDER FRYE V. UNITED STATES, IN THAT THE COMMISSION MADE NO FINDING, AS REQUIRED UNDER FRYE, THAT EDTA CHELATION THERAPY RESTS ON SCIENTIFIC METHODOLOGY GENERALLY ACCEPTED IN THE SCIENTIFIC FIELD IN WHICH IT BELONGS; AND (B) RESPONDENT'S EXPERT WITNESSES TESTIFIED IN TERMS OF CHELATION MEETING THE "STANDARD OF CARE" AND FAILED TO FRAME THE THEIR TESTIMONY IN TERMS OF THE STATUTORY LANGUAGE OF SECTION 334.100.2(5), RSMo, TO-WIT: "THAT DEGREE OF SKILL AND LEARNING ORDINARILY USED UNDER THE SAME OR SIMILAR CIRCUMSTANCES BY THE MEMBERS(S) OF THE . . . LICENSEE'S PROFESSION," AND THEREFORE THERE IS NO COMPETENT AND SUBSTANTIAL EVIDENCE IN THE RECORD TO SUPPORT THE COMMISSION'S FINDINGS THAT EDTA THERAPY IS EFFECTIVE.

(1) Section 490.065 Only Applies in Civil Cases.

The Court of Appeals did not deal with the fact that Section 490.065 expressly applies only to civil cases and that this case was not a civil case.

> 490.065. **Expert witness, opinion testimony admissible– hypothetical question not required, when**.
>
> 1. In any civil action, if scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise. (Emphasis supplied)[1]

[1]It is interesting to note that the Commissioner, in citing Section 490.065, quoted in his conclusions of law the entirety of Section 1 of 490.065 *except for* the qualifying phrase "in any civil action."

The argument that the *Daubert* standard[2] should replace the *Frye* standard[3] turns on the question of whether the Legislature intended that the standards enunciated in Section 490.065, RSMo 1994, should supercede the requirements of *Frye.* Section 490.065 applies on its face only to the trial of civil actions. The hearing in the present case was not the trial of a civil action. It was an "agency proceeding," as so denominated by the Legislature. It was not a civil action tried in a court before a judge.

It has been held that the Missouri Supreme Court's rules for civil actions in circuit court have no force of law before the Administrative Hearing Commission ("AHC"). *Dorrell Re-Insulation v. Director of Revenue*, 622 S.W.2d 516, 518 (Mo. App. W.D. 1981); *Dillon v. Director of Revenue*, 777 S.W.2d 326, 329 (Mo. App. W.D. 1989). Of course, the Legislature may specifically incorporate them by reference. *Wheeler v. Board of Police Comm'rs*, 918 S.W.2d 800, 803 (Mo. App. W.D. 1996). "The rules of civil procedure by the very terms of promulgation apply only to civil actions in judicial courts." (*Id*.)

"A proceeding for judicial review of an administrative decision does not become a civil action so as to be entitled to the melioration of the civil rules of procedure until the appeal lodges with the court and within the time prescribed by the legislative act which enables the appeal." *Dorrell Re-Insulation*, 622 S.W.2d at 518; citing, *Randles v. Schaffner*, 485 S.W.2d 1, 3 (Mo. 1972). "The rules of civil procedure have no function in a proceeding still

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[2] *Daubert v. Merrell Dow Pharmaceutical, Inc*, 509 U.S. 579, 113 S.Ct. 2786 (1993).

[3] *Frye v. United States*, 293 F. 1013 (D.C. 1923).

administrative. *Dorrell R-Insulation*, 622 S.W.2d at 518; citing, *Cardinal Glennon Memorial Hospital Coffee Shop v. Director of Revenue,* 624 S.W.2d 115 (Mo.App. W.D. 1981).

In Section 536.085, RSMo 1994, the Legislature defines the term "Agency proceeding."

> "Agency proceeding", an adversary proceeding in a contested case (as defined in the Administrative Procedure Act) pursuant to this chapter in which the state is represented by counsel, but does not include proceedings for determining the eligibility or entitlement of an individual to a monetary benefit or its equivalent, child custody proceedings, eminent domain proceedings, drivers license proceedings, vehicle registration proceedings, proceedings to fix a rate, or proceedings before the state tax commission.

Under Section 536.087, RSMo 1994, covering the right to recover attorneys fees and expenses to a prevailing party, the Legislature distinguishes between an "agency proceeding" and a "civil action arising therefrom." It is clear that the Legislature does not consider an "agency proceeding" to be a civil action while in the administrative process. Only when a court action is placed on file on a petition for review does a licensing case become a "civil action."

As a further matter Chapter 536 contains some special rules of evidence applicable to "agency proceedings." For example, the act provides a special version of the business records

rule. Section 536.070, RSMo 1994. It has been held that an agency should follow the requirements for admitting business records as exceptions to the hearsay rule in administrative proceedings rather than the rules for admitting such records in court proceedings. *Associated Wholesale Grocers v. Moncrief*, 955 S.W.2d 37 (Mo. App. S. D. 1997).

Throughout Chapter 536, the Legislature distinguishes between an "agency proceeding" and a "civil action in circuit court." If a subpoena must be enforced, it must be enforced in a circuit court "in the same manner as though said subpoena has been issued in a civil case in the circuit court." Section 536.077, RSMo 1994. Similarly, Section 536.073, RSMo 1994, provides that "[i]n any contested case before an agency created by the constitution or state statute, any party may take and use depositions in the same manner, upon and under the same conditions, and upon the same notice, as is or may hereafter be provided for with respect to the taking and using of depositions in civil actions in the circuit court . . . ."

The AHC is not a court. Decisions in the AHC are rendered by appointed Commissioners, not judges. A proceeding in the AHC is not a civil case, plain and simple. Since the Legislature made a clear distinction in the APA between rules applicable to an "agency proceeding" and rules applicable in a "civil action in circuit court," and since the same Legislature specifically limited the applicability of Section 490.065, RSMo 1994, to civil actions, then Section 490.065 by definition has no applicability to hearings conducted in "agency proceedings." Therefore, Section 490.065 cannot have been intended by the Legislature to supplant the requirements of *Frye* in "agency proceedings." Section 490.065 had no applicability to the question of the admission of respondent's expert testimony at the

hearing in this case. *Frye* was applicable in the present case. If Section 490.065 was intended by the Legislature as a repudiation of *Frye* in civil cases, which is highly debatable, it is clear that it was not intended to apply in administrative proceedings.

Query: Did the legislature intend to have *Frye* apply in criminal cases, family law cases, and agency proceedings but something like *Daubert* apply in civil cases? The fact that Section 490.065 was limited to civil cases strongly suggests that the legislature was not intending to replace *Frye*. What would be the logic of a system where two different standards for scientific evidence were required?

Contrary to the claim made by Dr. McDonagh, appellant State Board of Registration for the Healing Arts ("Board") did in fact make an objection to the respondent's expert evidence based on *Daubert*. (*Petitioner's Motion in Limine Regarding the Admissibility of Expert Testimony,* R. at 49). This objection was stated in the written motion and also orally by counsel at the beginning of the hearing:

> "In the alternative, even if we look at it in terms of the newer Daubert vs. Merrill Dow standard that the United States Supreme Court has endorsed for federal courts, that many other states have adopted, we still believe that the scientific evidence in support of chelation does not meet the Daubert standard. We'll file a formal motion to that effect."

(Tr. 6).

When Dr. McDonagh called Dr. James P. Frackleton to the witness stand, counsel for

the Board made the following record:

> **MR. BRADFORD**: Along that line, if we're going to have Dr. Frackleton, can I make one objection to his testimony as I understand he's going to testify in support of chelation. My objection based on the Frye rule and Daubert rule would apply and be a running objection.
>
> **COMMISSIONER REINE**: Well, I thought what I would do–yes, you can do that–what I thought I would do would be take this with the case and take all the evidence subject to this–
>
> **MR. BRADFORD**: Subject to that objection.
>
> **COMMISSIONER REINE**: –subject to this objection, written objection.
>
> **MR. BRADFORD**: That would be fine.
>
> **COMMISSIONER REINE**: And that will take care of the problem.
>
> **MR. BRADFORD**: Well, if I'm not risking waiver, I won't open my big mouth any more."

> **COMMISSIONER REINE**: I don't think you risk any waiver. Then I'll docket this reply and we'll rule on that prior to the time we rule on the case or in the same order.

(Tr. 579-80).

In addition, the failure of Dr. McDonagh's proof to meet the *Daubert* standard was discussed at length in the *Reply Brief* filed by the Board in the Court of Appeals. Under the provisions of Section 536.070(7), RSMo Supp. 1997, evidence to which an objection is made before the AHC is nonetheless "heard and preserved into the record, together with any cross-examination . . . ." The Board's *Frye* motion was thus noted and taken with the case. The Board's *Frye* objection was treated as a continuing objection. (Tr. 689-90).

Contrary to the claim of Dr. McDonagh, the Board did specifically object to all of his literature on EDTA chelation therapy. (Tr. 689-90). When the literature was offered into evidence by Dr. McDonagh's counsel, the Board's counsel stated on the record: "I perhaps should make clear, subject, of course, to my continuing objection based on the Frye rule." The Commissioner responded: "That's understood. It applies to testimony and the exhibits." (Tr. 690). In a discussion of the literature offered by both sides, counsel for respondent reserved a foundation objection and counsel for the Board noted: "Right. And I have my objection based on the fact on the Frye rule that hers doesn't come in anyway because it doesn't meet the Frye rule." (Tr. 575).

Dr. McDonagh has repeatedly quoted Dr. Rudolph's estimate that 2% of physicians use

EDTA chelation therapy in their practices. Dr. McDonagh's expert witness Dr. Frackleton testified that there were 750 members of ACAM, the chelationists' organization in the United States, and perhaps another 250 physicians practicing chelation therapy who were not members of ACAM. Dr. Frackleton testified that there were approximately 1000 physicians in the United States using chelation therapy. (Tr. 722). He testified that (as of 1997) there were approximately 750,000 practicing physicians in the United States. (Tr. 723). If Dr. Frackleton is correct, then only about .00133% of physicians in the United States use EDTA chelation therapy in their practices. The Board believes that Dr. Frackleton's estimate is more accurate than Dr. Rudolph's estimate.

(2) Commissioner Reine Made No Finding Under the *Frye* Standard that the Investigatory Methodology Used by Dr. McDonagh's Experts is Generally Accepted Within the Medical Profession, or that EDTA Chelation Therapy Itself is Generally Accepted in the Medical Profession for the Treatment of Vascular Diseases.

Commissioner Reine made no finding under *Frye* that the methodology used by Dr. McDonagh's experts is generally accepted within the medical profession, or that EDTA chelation therapy itself is generally accepted in the medical profession for the treatment of vascular diseases. The failure to make such a finding is an abuse of discretion. *M.C. v. Yeargin*, 11 S.W.3d 604, 619 (Mo. App. E.D. 1999).

Indeed, Commissioner Reine could not have made such findings on the record made in

the AHC because the evidence was uncontroverted that neither the chelationists' methodology of purported medical research nor the efficacy of EDTA chelation therapy itself is generally accepted in the medical profession. This Court should reverse the Commissioner's findings on chelation therapy and remand to the Commission for the entry of new findings of fact and conclusions of law on the chelation issues, excluding any reliance on the testimony of Dr. McDonagh and his experts in support of chelation therapy.

(3) Dr. McDonagh's Expert Testimony Not Admissible Even Under Daubert Standard.

The Court of Appeals stated in its opinion that the Board did not contend that Dr. McDonagh's expert testimony did not meet the *Daubert* standards. In fact, the objection made at trial did in fact include the argument that Dr. McDonagh's expert witness testimony did not meet the requirements of *Daubert*. Also, the Board's *Reply Brief* in the Court of Appeals included a detailed discussion as to why Dr. McDonagh's expert testimony did not meet the requirements of *Daubert*.

The main reason that chelation therapy has met with a total rejection by the vast majority of physicians is that chelation proponents have not in fact followed the scientific method. The testimony of Dr. McDonagh's expert witnesses was not based on "good science." EDTA chelation therapy has been overwhelmingly rejected by the medical profession based on generally accepted controlled trials which have demonstrated that the therapy is not effective in the treatment of vascular disease.

The Board's expert witness, Dr. David G. Meyers, an expert in the field of epidemiology and biostatistics, testified that medical science demands that the best possible study be performed to prove that a drug or treatment works. (Tr. 72; Tr. 111, line 1, to Tr. 112, line 4). Dr. Meyers testified that "the scientific method dictates that we must prove that a treatment . . . works." (Tr. 88). This would mean that the evidence required to support chelation therapy is the most valid scientifically that is attainable. (Tr. 111, line 1, to Tr. 112, line 4).

In the case of chelation therapy, this would require a controlled trial establishing the efficacy of the therapy. (*Id*.) According to Dr. Meyers, there is no reason that a controlled trial could not be completed. (Tr. 108, line 10, to line 13). A physician cannot ethically rely on a case history or patient or physician testimonials if it is possible to conduct a study higher up on the scale of medical and scientific proof. Since a controlled trial is possible in the case of chelation therapy, a practicing physician may not rely on lesser forms of investigation.

Of course, in the present case, not only is a controlled trial possible, several have in fact been conducted and the findings reported in peer reviewed journals. The medical profession has accepted the Guldager and Van Riz controlled trials as establishing that chelation therapy is not effective in the treatment of vascular diseases.

(4) <u>Dr. McDonagh's Experts Fail to Testify in the Specific Terms of the "Objective Legal Standard" of the Statute</u>.

Dr. McDonagh argues that the Board has waived this issue because it failed to object to

the expert testimony on this ground at the hearing. Of course, the Board's appeal here addresses whether the expert testimony constitutes substantial evidence. Where the objection is not to the admissibility of expert testimony but rather to its legal sufficiency, no objection at the time of the testimony is required. *Washington by Washington v. Barnes Hosp.*, 897 S.W.2d 611, 616 (Mo. Banc 1995). The Board was not required to object to preserve this issue. Although evidence received without objection may be considered under Section 536.070.(8), RSMo, if it has "probative value," evidence that does not constitute substantial evidence does not have probative value by definition.

Section 334.100.2(5), RSMo, defines "repeated negligence" as "the failure, on more than one occasion, to use that degree of skill and learning ordinarily used under the same or similar circumstances by the member (sic) of . . . licensee's profession." The Board's expert, Dr. David G. Meyers, specifically testified that the term "standard of care," as he used it in his testimony, equated to the statutory language of "the failure to use that degree of skill and learning ordinarily used under the same or similar circumstances by the members of the licensee's profession." (Tr. 174-76). Section 334.100.2(5), RSMo. Therefore, Dr. Meyers' testimony to the effect that Dr. McDonagh's care did not meet the standard of care constituted substantial evidence because it was tied to the statutory definition of negligence.

Dr. McDonagh failed to adduce substantial and competent evidence from his own experts to support the AHC's findings that his care met the applicable standards of care, in that Dr. McDonagh's experts (including Dr. McDonagh himself) spoke generally in terms of Dr. McDonagh's conduct "meeting the standard of care," without otherwise testifying that Dr.

McDonagh acted in accordance with "the skill and learning ordinarily used under the same or similar circumstances by the member(s) of . . . a licensee's profession."

In *Swope v. Printz*, 468 S.W.2d 34 (Mo.1971), an expert witness was asked, "Do you have an opinion of whether or not the operation as performed by Dr. Printz was up to acceptable medical standards as you know them?" The expert answered that the operation "was not up to acceptable medical standards." The Missouri Supreme Court reversed a plaintiff's verdict because it was not clear the expert was comparing the defendant's performance with the objective legal standard of negligence. 468 S.W.2d at 40. The Court of Appeals followed the precedent of *Swope v. Printz* in deciding *Bever v. State Board of Registration for the Healing Arts*, 2001 WL 68307*7 (W.D. Mo. January 30, 2001)(WD57880) and *Ladish v. Gordon*, 879 S.W.2d 623 (Mo. App. W.D. 1994).

(5) Respondent's Response on "Standard of Care" Issue.

Even if the *Bever* case is not authoritative, it is certainly instructive. In any event, the *Bever* court simply extended the principles previously announced in *Swope v. Printz*, *Ladish v. Gordon*, and like cases. In *Ladish v. Gordon*, the Court of Appeals stated: "In order to establish her prima facie case, Plaintiff Ladish bears the burden of proving that Dr. Gordon failed to exercise that degree of skill and learning ordinarily exercised by members of his profession under the same or similar circumstances in treating her condition." 879 S.W.2d at 628; citing, *Cebula v. Benoit*, 652 S.W.2d 304, 307 (Mo.App.1983). "The opinion of a medical expert must have sufficient probative force to constitute substantial evidence." *Pippin v. St. Joe Minerals Corp.*, 799 S.W.2d 898, 904 (Mo.App.1990).

Dr. McDonagh further tries to distinguish *Bever* on the basis that Dr. Bever admitted the content of the standard of care on some of the issues in his own testimony, which the Court of Appeals held relieved the Board of having to prove up the standard of care on those particular issues. *Ladish v. Gordon* stands for the proposition that the party with the burden of proof on the issue of the standard of care is relieved of the burden if the responding party, as an expert himself in his own right, or an expert testifying for him, admits the content of the standard of care. In *Bever*, the Court found that there was really no disagreement as to the content of the standard of care on a number of patient care issues. The disagreement was with whether Dr. Bever had complied with the standard of care.

In contrast to *Bever*, here the parties endeavored to prove up totally different and mutually exclusive standards of care. The Board sought to prove that the use of EDTA chelation therapy to treat vascular diseases is not within the standard of care. The Dr. McDonagh sought to prove just the opposite.

> "Q ***As you know (Dr. Frackleton), we say that the standard of care is that you don't treat atherosclerosis with EDTA. That's our allegation. Now, as I understand it, you don't agree with that?
>
> A I don't agree with that.
>
> Q And you say that it is permissible to treat atherosclerosis with

EDTA, correct?

A It's recommended."

The *Ladish v. Gordon* exception is not applicable here. The disagreement here was about the content of the standard of care itself.

Swope v. Printz and *Ladish v. Gordon* established the principle that expert medical testimony couched in terms of the "standard of care," without defining that term in terms of the applicable legal standard, the failure "to exercise that degree of skill and learning ordinarily exercised by members of his profession under the same or similar circumstances," does not amount to substantial evidence. The *Bever* opinion merely logically and appropriately extended the principle to administrative hearings.

POINT II.

THE ADMINISTRATIVE HEARING COMMISSION ERRED IN FINDING THAT EDTA CHELATION THERAPY MEETS THE STANDARD OF CARE FOR THE TREATMENT OF ATHEROSCLEROSIS AND OTHER VASCULAR DISEASES, BECAUSE EDTA CHELATION THERAPY IS NOT GENERALLY ACCEPTED WITHIN THE MEDICAL PROFESSION AS EFFECTIVE IN THE TREATMENT OF ATHEROSCLEROSIS OR OTHER VASCULAR DISEASES, AND, IN ADDITION, WHILE THERE MAY OR MAY NOT BE A "GOOD FAITH DISPUTE AMONG COMPETENT PHYSICIANS" AS TO THE EFFECTIVENESS OF EDTA CHELATION THERAPY FOR THIS USE, IN THAT

THE USE OF EDTA CHELATION THERAPY TO TREAT ATHEROSCLEROSIS OR OTHER VASCULAR DISEASES IS NONETHELESS "AGAINST THE COURSE RECOGNIZED AS CORRECT BY THE MEDICAL PROFESSION GENERALLY," AND SUCH TREATMENT THEREFORE DOES NOT MEET THE STANDARD OF CARE UNDER MISSOURI LAW; THEREFORE, ON THIS ISSUE THE AHC ERRONEOUSLY ANNOUNCED AND APPLIED LAW.

(1) Dr. McDonagh's Experts Could Not Legitimately Testify That His Patient Care Was Within The Standard of Care.

The failure to qualify respondent's expert testimony in the terms of the statute is no mere technical flaw in the context of the present case. It is plain that Dr. McDonagh's experts could not legitimately have claimed that EDTA chelation therapy to treat vascular disease meets the standard of care as defined in the statute. The standard of care is what is generally done and accepted in the medical profession. If a treatment is not generally accepted in the medical profession, it cannot meet the standard of care. *McReynolds v. Mindrup*, 108 S.W.3d 662, 667-68 (Mo.App. W.D. 2002).

Dr. Frackleton admitted that chelation therapy is not generally accepted by either the allopathic or osteopathic branches of the medical profession as an acceptable treatment for vascular disease. What Dr. McDonagh's experts were really saying is that EDTA chelation therapy is accepted as meeting the "standard of care" by those physicians who use the therapy in their practices. This separate and distinct "standard of care" is represented by the Protocol

for EDTA Chelation Therapy promulgated by the American College for Advancement in Medicine (ACAM). (Tr. 756-59).

> "Q All right. Well, let's look at some of the standards. So what you're saying is the standard of care is actually the protocol understanding that the physician has room to vary it in an appropriate situation; is that fair?
>
> A Yes."

(Tr. 759) (Dr. Frackleton).

The Court of Appeals for the Western District decided last year the case of *McReynolds v. Mindrup*, supra, which involved issues similar to those in the present case. The plaintiff sought to use the expert testimony of a treating dentist. The Western District had these words:

> "Dr. Kennedy is a licensed dentist, and his testimony reflects that he is aware of the standards followed by the vast majority of the dental community. Appellants' pleadings reflect that they were going to rely on Dr. Kennedy's testimony to establish the proper standard of care. By definition, the standard of care must be generally accepted by the relevant medical community, in this instance, the dental community. The practice and beliefs of a limited number of members of the profession does not constitute the appropriate standard of care. To the extent that Dr.

> Kennedy wishes to testify regarding his opinion that the standard of care generally recognized by his profession is inappropriate, the trial court may well determine that such testimony should be excluded as irrelevant to whether Dr. Mindrup followed the currently accepted standard of care in his profession."

108 S.W. 3d 662, 667-68 (emphasis supplied).

The evidentiary situation present in *McReynolds v. Mindrup* is precisely the situation present here. The experts for the Dr. McDonagh were really saying that, while the standard of care in the medical profession rejects chelation therapy as a treatment for vascular disease, that standard in inappropriate. As a further matter, Dr. McDonagh's experts were in effect arguing for an alternative standard of care as represented by the ACAM Protocol. Dr. McDonagh's experts could not in good conscience have claimed that chelation therapy is generally accepted in the medical profession for the treatment of vascular disease. Indeed, Dr Frackleton, Dr. McDonagh's primary expert, admitted that it is not generally accepted in the medical profession.

Dr. McDonagh's primary expert witness, Dr. James P. Frackleton, M.D., squarely admitted that EDTA chelation therapy is not generally accepted in the medical profession in this country as efficacious for the treatment of atherosclerosis. (Testimony of Dr. James P. Frackleton, Transcript, page 713, line 9, to page 714, line 5)

"Q. My question is this. Can we agree that the use of EDTA chelation to treat atherosclerosis is not at this point in time generally accepted in the medical profession in this country as efficacious for the treatment of atherosclerosis?

A. I would think that's probably true through ignorance of their part.

Q. I understand you don't agree with it and we'll talk about that.

A. I agree with your statement but it's through their ignorance, yes.

Q. I understand you don't think that's right, but it is at this point in time not generally accepted in the medical profession; that's the case, is it not?

A. I would think so, certainly.

Q. And that's been true in the allopathic end of the business, which you're an MD and you belong to, and the osteopathic end of the business for DOs like Dr. McDonagh; is that a fair statement?

A. True."

(Testimony of Dr. James P. Frackleton, Tr. 713, line 23, to Tr. 714).

(2) Testimony that Dr. McDonagh's Patient Care "Met the Standard of Care."

The Board has carefully searched the trial transcript in an attempt to determine precisely what the disqualification of Dr. McDonagh's expert testimony as to his compliance with the "standard of care" would do to the AHC's specific findings and conclusions. The issue of the lack of a definition of "standard of care" would apply to the trial testimony of Dr. Terry Chappell and Dr. McDonagh, himself.

Dr. Terry Chappell testified as an expert witness for Dr. McDonagh. Dr. Chappell testified that Dr. McDonagh's care for Lloyd Jones "met the standard of care." (Tr. 839). Likewise, Dr. Chappell testified that Dr. McDonagh's care of Beverly Collins "met the standard of care." (Tr. 841). Dr. Chappell testified that Dr. McDonagh's care of Joseph Hoskins "met the standard of care." (Tr. 842). Dr. Chappell testified that in Dr. McDonagh's care for Ruby Triggs "the standard of care was met." (Tr. 843). For patient Geraldine Hamilton, Dr. Chappell testified that Dr. McDonagh's care "met the standard of care." (Tr. 844). Likewise, Dr. Chappell testified that Dr. McDonagh's care of Thomas Gerrity "met the standard of care." (Tr. 846). Similar testimony was given in respect to Dr. McDonagh's care of Lucille McCarty, said by Dr. Chappell to have "met the standard of care." (Tr. 847). Further, Dr. Chappell testified that Dr. McDonagh's care of Donald Starkenburg "met the standard of care." (Tr. 848). The same type of summary testimony was given in the case of patient James

Crimmings (Tr. 849), to the effect that Dr. McDonagh "met the standard of care."

Nowhere in Dr. Chappell's testimony did he explain what he meant by the term "standard of care." Nowhere did Dr. Chappell attempt to define his use of the term "standard of care" in light of the statutory definition, "the failure *** to use that degree of skill and learning ordinarily used under the same or similar circumstances by the member (sic) of . . . licensee's profession."

Dr. McDonagh himself testified that his treatment of patient Lloyd Jones "met the standard of care." (Tr. 1011). With respect to patient Beverly Collins, Dr. McDonagh testified that his care "met the standard of care." (Tr. 1032). Dr. McDonagh also claimed that his care for Joseph Hoskins "met the standard of care." (Tr. 1040). The same conclusory testimony was given for the treatment provided to patients Ruby Triggs (Tr. 1055-56), Gerry Hamilton (Tr. 1066), Thomas Gerrity (Tr. 1073), Lucille McCarty (Tr. 1079, 1081 ("that was top-notch care"), 1090), and James Crimmings (Tr. 1099).

Nowhere in Dr. McDonagh's testimony did he explain what he meant by the term "standard of care," or "top-notch care." Nowhere did Dr. McDonagh attempt to define his use of the term "standard of care" in light of the statutory definition, "that degree of skill and learning ordinarily used under the same or similar circumstances by the member (sic) of . . . licensee's profession."

It does not appear that either Dr. Frackleton or Dr. Rudolph testified in terms of Dr. McDonagh's care "meeting the standard of care" at all, either with the appropriate statutory definition or without. The testimony of Dr. Frackleton and Dr. Rudolph was of a broad, general

nature and did not speak to the specific legal question in issue, to-wit: whether Dr. McDonagh failed "to use that degree of skill and learning ordinarily used under the same or similar circumstances by the member (sic) of . . . licensee's profession."

Therefore, Dr. McDonagh presented two experts who failed to define their terms and two experts who failed to offer testimony on the issue at all. As such, the testimony of the Board's expert witness was effectively uncontroverted. Dr. McDonagh's expert testimony that his care "met the standard of care" was presented as to all counts of the Board's Complaint specifically related to a particular patient's care, including Counts II, III, IV, V, VII, VIII, IX, X, XI, XII, and XIII (repeated negligence). There was therefore inadequate substantial evidence to support the Commissioner's findings of fact on these counts.

(3) Who Decides if EDTA Chelation Therapy is Safe and Effective, the Medical Profession or Commissioner Reine? Commissioner Reine Arrogates to Himself the Responsibility to Determine if EDTA Chelation Therapy Effective.

An issue in this case is the issue of whether or not the personal testimonials of patients can constitute competent and substantial evidence. The Commissioner was clearly influenced by the testimonials of certain of Dr. McDonagh's patients, who claimed positive results from chelation therapy. In his *Respondent's Brief*, Dr. McDonagh claims that patient testimony provides sufficient substantial and credible evidence to sustain the Commissioner's findings that chelation has been helpful to some patients, even in the absence of expert testimony. Of course, without expert testimony on causation, there is absolutely no basis to attribute

perceived improvements in health to this particular treatment. A layman is clearly not qualified to determine whether improved health or continued good health is the result of any particular treatment.

Interestingly, the Commissioner relies on the case of *Rogers v. State Bd. of Medical Examiners*, 371 So.2d 1037 (Fla. Dist. Ct. App. 1979), the decision of the intermediate appellate court, but mentions in a footnote that in the *Rogers* case the Board refused to hear any patient testimony.

> "The Board had refused to hear any patient testimony. One Board member stated: 'I think having a string of patients come up with anecdotal stories about how much better they felt the next day or the next year would not be admissible in any scientific inquiry into the effectiveness of any mode of treatment, and I think that would not be helpful, nor would it protect the rights of the petitioner, or the health of the patients . . . . Patients themselves are not competent to make those judgments.' *Rogers*, 371 So.2d at 1041."

(AHC *Findings of Fact and Conclusions of Law*, Appendix 1 to *Respondent's Brief*, at p. A41, Footnote 121). Despite an ultimate finding in favor of Dr. Rogers, and despite the Commissioner's implication, it does not appear from the Florida Court of Appeals' opinion

that the court ultimately took issue with the decision of the Board to refuse to hear patient testimony.

In *Crum v. State Board of Medical Registration and Examination*, 37 N.E.2d 65 (Ind. 1941), the Indiana Supreme Court reviewed the action of the Indiana State Board in revoking the license of one Heil Eugene Crum. Dr. Crum had invented and used in his medical practice a machine called an "etherator" or "coetherator," which was found by the Board and the trial court to be absolutely devoid of therapeutic value. The device was basically an empty wooden box with non-functional knobs and levers on the outside. The Indiana Supreme Court had these words as to the value of patient testimonials:

> The mention of the extravagant claims made by the appellant is sufficient to suggest their untruthfulness and brand them as designedly fraudulent. His case is not helped by the fact that he has produced numerous witnesses at trial who voluntarily testified as to miraculous cures that had been brought about by the use of his machine. 'Hope springs eternal in the human breast,' and it is not uncommon for persons who are afflicted with dreadful diseases to be misled and beguiled into believing that they have been helped by quacks and charlatans.

37 N.E.2d at 68. The Indiana Supreme Court concluded that "[i]t is reasonable to suppose that

by the enactment of the Medical Practice Acts, it was the deliberate purpose of the General Assembly to protect such unfortunate people from their own credulity." *Id.* As demonstrated in *Crum* v. *State Board*, patients are often so anxious to regain their health that they will line up to testify to the miraculous healing powers of an empty box.

Ordinarily, proof of causation must be made by way of expert testimony. *Landers v. Chrysler Corp*., 963 S.W.2d 275, 279 (Mo. App. E.D. 1997). Medical causation, which is not within the common knowledge or experience of laymen, must be established by scientific or medical evidence showing the cause and effect relationship between the complained of condition and the asserted cause. *McGrath v. Satellite Sprinkler Systems Inc.*, 877 S.W.2d 704, 708 (Mo.App. E.D. 1994); *Bever*, supra, at *5. Proper opinion testimony as to causal connection is competent and can constitute substantial evidence. *Landers,* supra, 963 S.W.2d at 279.

It is clear that the issue of the effectiveness of chelation therapy in the treatment of vascular disease, is not an issue within the competency of a lay witness. *Knipp v. Nordyne, Inc.,* 969 S.W.2d 236, 240 (Mo.App. W.D. 1998). The principles established in the personal injury cases apply in the present case. A patient with no medical or scientific training or background is not competent to testify as to the medical cause of a particular condition or state of health, even his own.

A lay patient's affidavit submitted on causation has been held not to constitute substantial evidence sufficient to outweigh contrary expert testimony in the consideration of a motion for summary judgment. *Greene v. Thiet,* M.D., 846 S.W.2d 26 (Tx. App. 1992). The

medical conclusions of a lay witness cannot controvert the opinion of an expert on medical issues. *Id.* A lay witness in not competent to testify on complicated medical issues related to causation. *Id.*

The significant question is whether the care in question produces an objectively measurable modification of the disease process. Absent expert testimony attributing a modification of the disease process (as opposed to the subjective impressions of the patient) to a particular treatment, the Commissioner had no basis for finding that EDTA chelation therapy had indeed "helped" patients, other than as perhaps a very expensive placebo.

(4) Commissioner Reine Finds That "Something" Is Helping Patients.

Commissioner Reine concluded that "something" is helping these people get better. However, that "something" might well be diet, exercise, vitamins, mineral supplements, or some combination thereof. Although Dr. McDonagh's experts conceded that the presence of confounding variables would make it impossible to assess the effects of EDTA chelation therapy in a clinical setting, the Commissioner nevertheless was swayed by this type of evidence. Commissioner Reine states that "something" is helping these patients. The Board did not question the efficacy of "something."

The Board has no quarrel with advising patients to eat a healthy diet or to begin a program of regular exercise. "Something" might be helping some of these patients but nobody, expert, layman, or AHC Commissioner, can say that EDTA chelation therapy plays a role in helping clinical patients.

In addition to a basic issue of the competence of a lay witness to attribute results to particular therapies, the two patients in the present case also had what scientists describe as "confounding variables," which would make attribution of their continued good health to the chelation treatments scientifically unsupportable.

Both Geraldine Hamilton and Tom Gerrity adopted regimens of strict diet and consistent exercise, in addition to continuing medications prescribed by their cardiologists. In everyday language, there were too many other factors which could have been responsible to give all the credit to the chelation therapy. In particular, medical science has long since accepted the results of testing which demonstrated that exercise alone–and diet alone–can help alter the progression of atherosclerosis. (Dr. Frackleton's Testimony, Tr. 706). Therefore, there would be no way to attribute patient improvement to the chelation in and of itself.

On the issue of "confounding variables" for clinical patients based on the general use of exercise, diet, and vitamin therapy, Dr. James P. Frackleton testified as follows:

> "Q But on any given patient, on any given patient, there would be no way to fairly say that it's due to the chelation per se, would there?
>
> A I would agree with that."

(Tr. 706-10).

Dr. Frackleton's testimony on this issue would seem to be wholly at odds with the Commission's apparent conclusion that patient testimony alone can provide substantial

evidence to support the Commissioner's finding that EDTA chelation therapy complies with the standard of care in the treatment of circulatory disease.

Commissioner Reine credits chelation with benefitting some patients, although acknowledging that diet and/or exercise might be responsible for any good results. (FOF, page 42). These are inherently inconsistent findings. Even Dr. Frackleton admitted that case reports on chelation are subject to the error of "confounding variables." (Tr. 709). Additionally, Dr. Charles Rudolph, the expert witness who provided the examples of patient improvement which Commissioner Reine ultimately relied on, acknowledged that the course of EDTA chelation therapy also includes diet, exercise, and vitamins and minerals, and he admitted that none of the work done in his office in the study of EDTA chelation was done studying purely the effect of EDTA chelation in and of itself. (Tr. 1366).

(5) State Regulation of the Practice of Alternative Medicine–What Are the limits of a Physician's Right to Provide Whatever Treatment He Wishes Without Regard to the Established Standard of Care.

Dr. McDonagh relies heavily on the case of *Rogers v. State Board of Medical Examiners*, supra. There, a Florida court held that a patient was entitled to choose to be treated with chelation therapy, and that the State Board of Medical Examiners could not discipline a physician's license because of offering a type of treatment not meeting the applicable standard of care, where there was no evidence of patient harm and where the physician was candid with his patients as to the limitations on the scientific support for the use of chelation. The court

found that the Board sought to limit Dr. Rogers' use of chelation because it had not been proven effective and therefore its use did not conform to "the standards of acceptable and prevailing medical practice in his area of expertise . . .". The court held that the state's limitation on the use of chelation therapy was not shown to have a reasonable relationship to the protection of the public health and welfare.

The biggest distinction between the *Rogers* case and the present case is that there were no substantial controlled trials back in 1979. Before the present case was filed, the Guldager and Van Riz studies were published, both of which were generally accepted by the medical profession and both of which showed no patient improvement due to chelation therapy. In contrast to the situation in *Rogers*, where the Florida Board contended that chelation therapy had simply not been proven effective, the present record shows that chelation therapy has been authoritatively proven to be ineffective.

CONCLUSION

For the reasons set forth above, Appellant prays that this Court reverse the Findings of Fact and Conclusions of Law of the Administrative Hearing Commission and remand this case back for new findings of fact and conclusions of law consistent with this Court's opinion.

_____
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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing was mailed, postage prepaid, this ___ day of September, 2003, to:

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CERTIFICATE OF COMPLIANCE

Pursuant to Missouri Supreme Court Rule No. 84.06(c), Appellant hereby certifies that this brief complies with the limitations contained in 84.06 (b) and that, according to the word count feature in WordPerfect, the entire brief contains _____ words. Appellant further certifies that, pursuant to 84.06(g), it is filing with this brief a computer disk which contains a copy of the above and foregoing brief, which was prepared using WordPerfect 8.0, and

Appellant also certifies that the disk has been scanned for viruses and is virus-free. This brief also includes the information required by Rule 55.03.

_____

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